

Translation

PATENT COOPERATION TREATY

PCT/JP2004/011006



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference T-531	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2004/011006	International filing date (day/month/year) 27 July 2004 (27.07.2004)	Priority date (day/month/year) 28 July 2003 (28.07.2003)
International Patent Classification (IPC) or national classification and IPC C08G 81/00 // C08L 71/00, A61F 2/30, A61L 27/00, A61K 47/00		
Applicant TEIJIN LIMITED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ (sent to the applicant and to the International Bureau) a total of 4 sheets, as follows:
 - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 24 February 2005 (24.02.2005)	Date of completion of this report 17 June 2005 (17.06.2005)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ The international application as originally filed/furnished

☒ the description:

pages _____ 1-3,7-10 _____, as originally filed/furnished
 pages* _____ 5,6 _____ received by this Authority on 28 February 2005 (28.02.2005)
 pages* _____ 4 _____ received by this Authority on 01 June 2005 (01.06.2005)

☒ the claims:

pages _____ 2 _____, as originally filed/furnished
 pages* _____, as amended (together with any statement) under Article 19
 pages* _____ 1 _____ received by this Authority on 01 June 2005 (01.06.2005)
 pages* _____ received by this Authority on _____

☒ the drawings:

pages _____ 1-5 _____, as originally filed/furnished
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement	Novelty (N)	Claims	1, 2	YES
		Claims		NO
	Inventive step (IS)	Claims	1, 2	YES
		Claims		NO
	Industrial applicability (IA)	Claims	1, 2	YES
		Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: JP 07-278203 A (Collagen Corp.)
24 October 1995

Document 2: Daniel Cohn, Alejandro Sosnik, Avraham Levy,
"Improved reverse thermo-responsive polymeric systms"
Biomaterials, Vol. 24, 2003, p. 3707-3714 (Elsevier Science Ltd.)

Document 3: Byeongmoon Jeong, Sung Wan Kim, You Han Bae
"Thermosensitive sol-gel reversible hydrogels"
Advanced Drug Delivery Reviews, Vol. 54, 2002, p. 37-51 (Elsevier Science B.V.)

The inventions of claims 1 and 2 are novel and involve an inventive step with respect to the documents cited in the international search report.

Document 1 cited in the international search report describes a biocompatible, biologically inert conjugate comprising a glycosaminoglycan or derivative thereof that is chemically bonded to a hydrophilic synthetic polymer. Document 1 also lists polyethylene glycol, polyoxyethylene-polyoxypropylene block polymer, etc., as the main chain of the above hydrophilic synthetic polymer, and it describes providing the reactive terminal of the above hydrophilic synthetic polymer with mono-functionality.

However, the hyaluronic acid derivatives specifically disclosed in document 1 (reaction schemes 5 and 6) only have a chemical structure wherein the above hydrophilic synthetic polymer residue is bonded to the amino group of hyaluronic acid, and document 1 neither describes nor implies the chemical structure of Formula (1) of claim 1 of this application wherein a polyether residue is bonded at the site of substituent R1. In addition, whereas the polyether chain described in document 1 is specified as hydrophilic, the polypropylene glycol of claim 1 of this application is hydrophobic (if necessary, see supplemental documents 2 and 3 presented by the applicant). Therefore, inventions utilizing the polypropylene glycol of this application are clearly beyond the scope of document 1 from the standpoint of hydrophilicity/hydrophobicity.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box V:

Furthermore, the differences between the invention of document 1 and the inventions of this application are additionally corroborated by the experimental report submitted to the International Preliminary Examining Authority dated 28 February 2005 wherein it is demonstrated that the hyaluronic acid derivative of document 1 does not form a hydrogel in response to temperature.

Based on the above, this examination finds that the inventions of claims 1 and 2 of this application are novel and non-obvious, they have excellent bioabsorbability and bioaffinity, and they can be applied advantageously in the field of reconstructive medicine, etc., by utilizing their specific property of forming a hydrogel in response to temperature.